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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Leland F. WILSON et al.

Confirmation No.: 9897

Serial No.: 09/929,818

Group Art Unit: 1654

Filing Date: August 13, 2001

Examiner: Billy D. CHISM

Title: TREATMENT OF FEMAL SEXUAL DYSFUNCTION WITH VASOACTIVE AGENTS, PARTICULARLY VASOACTIVE INTESTINAL POLYPEPTIDE AND AGONISTS THEREOF

RESPONSE TO REQUIREMENT FOR RESTRICTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This communication responds to the Restriction Requirement, mailed April 4, 2003, for the patent application identified above. A previous Restriction Requirement was mailed from the Office on October 30, 2002, requiring restriction between method claim 1-28 (Group I) and composition claims 29-40 (Group II). On January 6, 2003, applicants elected the claims of Group I without traverse. Sometime after the mailing of the first Restriction Requirement, this case was reassigned from Examiner Criares to Examiner Chism. On April 4, 2003, the new Examiner withdrew the previous Restriction Requirement and issued a new Restriction Requirement as follows:

Set I: inventions 1-204, claims 1-28, drawn to a method of treating female sexual disorders comprising administering any one of SEQ ID Nos. 2-204; and

Set II: inventions 205-408, claims 29-40, drawn to polypeptide compositions comprising any one of amino acid sequences of SEQ ID Nos. 205-408.

With this Restriction Requirement, the Examiner is requiring restriction of the application to a single nucleotide sequence to be searched for either Set I or Set II.

In response to the Restriction Requirement, applicants elect the claims of Set I, claims 1-28, with traverse. This election is made with the understanding that applicants expressly reserve the right under 35 U.S.C. § 121 to file a divisional application directed to the subject matter of nonelected claims 29-40 during the pendency of this application.

Applicants respectfully traverse the Restriction Requirement as improper on two grounds: the first being that the recited nucleotide sequences are ***not*** separate inventions within the context of this application, but rather, are ***species*** of the vasoactive intestinal polypeptides (VIPs) of the claimed pharmaceutical formulation; and the second being that the pursuant to the partial waiver of 37 C.F.R. § 1.114, the Commission has determined that a search of ***ten not one*** nucleotide sequences are reasonable for examination purposes.

Turning first to the issue of the partial waiver of 37 C.F.R. § 1.114, applicants direct the Examiner's attention to 1192 O.G. 68 (Nov. 19, 1996), which is reproduced in part at MPEP §§ 803.04 and 2435. The third paragraph of MPEP §§ 803.04, sets forth the Commissioner's view with respect to the restriction of nucleotide sequences with the following statement:

> It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

The foregoing excerpt demonstrates that the Commissioner does ***not*** find the restriction of an application to ***one*** nucleotide sequence to be reasonable, but rather, finds that the Examiners of the PTO can reasonably search for ***ten*** nucleotide sequences in any one patent application. Accordingly, the Examiner's requirement for restriction of this application to one nucleotide sequence is improper under Patent Office Rules and Policy.

Turning next to the Examiner's requirement for ***restriction*** of this application to one nucleotide sequence, applicants direct to the Examiner's attention to MPEP § 803.04 under the subheading "Examples of Nucleotide Sequence Claim," which provides guidance on the types of claims that are covered by restriction practice of claims reciting nucleotide sequences. There, three examples of nucleotide sequence claims covered by the partial waiver of 37 C.F.R. § 1.141 are reproduced as follows:

> (A) an isolated and purified DNA fragment comprising DNA having at least 95% identity to a DNA sequence selected from SEQ ID Nos. 1-1,000;
>
> (B) a combination of DNA fragments comprising SEQ ID nos. 1-1,000; and

> (C) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000.

These three claims clearly show that the types of claims that the Commissioner was contemplating under the partial waiver of 37 C.F.R. § 1.141 are claims that expressly recite the nucleotide sequences as constituting the inventive step and ***not*** claims that refer to nucleotide sequences as species, or embodiments (*see,* MPEP § 806.04(h)), of a separately patentable invention. On this matter, the Examiner' is reminded of the language of 37 C.F.R. § 1.41(a), which provides:

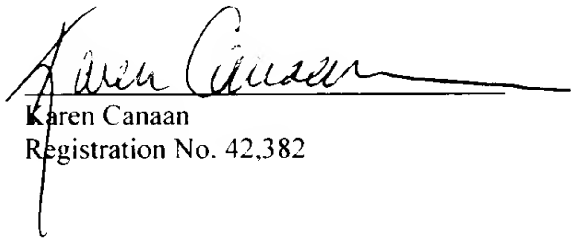
> Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided that application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim.

The instant application is drawn to two separately patentable inventions, i.e., the inventive method of claims 1-28 and the inventive composition of claims 29-40. This fact has been recognized by both Examiner Criares, with the Restriction Requirement of October 30, 2002, requiring restriction of the application to two groups of claims, Group I drawn to method claims 1-28 and Group II drawn to composition claims 29-40, and Examiner Chism, with the present Restriction Requirement requiring restriction of the application to two sets of claims, Set I directed to method claims 1-28 and Set II directed to composition claims 29-40. With respect to Examiner Chism's additional requirement for election of a nucleotide sequence for purposes of searching, this requirement appears to fall within the ambit of a species election, as SEQ. ID. NOS. 2-205 represent the different VIPs that may be used to prepare the claimed pharmaceutical formulation. In light of the foregoing, applicants submit that SEQ. ID. NOS. 2-205 are ***species*** of the invention and ***not*** inventions in their own right.

Accordingly, for purposes of expediting the prosecution of this application, and pursuant to the partial waiver requirement of 37 C.F.R. § 1.141, applicants provisionally elect the species of SEQ. ID. NOS. 2-11 for initial examination. This provisional election of species is made with the understanding that the election is solely for purposes of initial examination and that upon allowance of a generic claim, all species (Seq. Nos. 2-205) will be allowable.

If the Examiner has any questions concerning this communication, he is welcome to contact the undersigned attorney at (650) 330-4913.

Respectfully submitted,

By: 

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